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3,553,299 PROCESS OF PRODUCING SHAPED OPTICAL BODIES USEFUL AS AIDS TO VISION Heinrich Thiele, 16 Hardenbergstrasse, Kiel, Germany, and Wilhelm P. Soehnges, 11 Bluetenstrasse, Munich, No Drawing. Filed Dec. 12, 1967, Ser. No. 690,028 Int. Cl. B29d 11/00, 11/02

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#### ABSTRACT OF THE DISCLOSURE

Optical lenses useful for replacing damaged or cataractous eye lenses, contact lenses, and other aids to vision are obtained by first preparing a colloidal solution of the 15 peripheral part of animal or human eye lenses or of the lens nucleus or of both materials by means of aqueous solutions of acid or alkaline agents or salts such as alkali metal hydroxides, hydroxy carboxylic acids, for instance, lactic acid, tartaric acid, or citric acid, urea and its de- 20 rivatives, lithium thiocyanate, and others which increase the solubility of the lens substance in water without affecting and denaturating the lens protein.

The resulting sol is then exposed to ion diffusion preferably through ion-permeable membranes in the desired 25 shape whereby a gel is formed. Polyvalent metal ions and preferably copper, cadmium, zinc, and calcium ions are the preferred ions. Electrodialysis or change in the pHvalue of the sol by means of hydrogen ions may also be used for gel formation.

The resulting clear and transparent shaped gel with oriented filamentary protein molecules is then stabilized by cross-linking with agents such as formaldehyde, dialdehydes, diepoxides, and the like.

# BACKGROUND OF INVENTION

The present invention relates to a process of producing aids useful in improving or restoring vision and more 40 particularly to such aids to vision as contact lenses, lenses for optical correction of the eye and for replacement of the natural eye lens and the like, and to such products useful in improving or restoring vision.

Optical lenses, contact lenses, and other aids to vision 45 have been made of glass and also of plastic material. Lenses made of plastic material have the advantage over glass lenses that they are substantially unbreakable. However, they have the disadvantage that they are not as resistant to atmospheric influences and the action of 50 cleansing agents and the like as glass lenses. Like glass lenses they are products foreign to the human body and, therefore, are not well tolerated when brought in contact with the organism, i.e., the eye. It is well known, for instance, that contact lenses made of plastic material may 55 cause considerable irritation to the eye so that frequently their use is prohibited.

### SUMMARY OF INVENTION

It is one object of the present invention to provide a 60 process of producing a material useful in the manufacture of aids to vision such as contact lenses, lenses to replace the damaged or otherwise impaired natural eye lens, and the like, which material is well tolerated by the human eye and is not rejected when implanted into the eye or brought 65 in contact with the eyeball.

Another object of the present invention is to provide contact lenses made of the natural protein of the lenses of eyes of warm-blooded animals, said contact lenses having no irritating effect when contacting the eyeball.

A further object of the present invention is to provide reconstructed lenses to be implanted into the eye in place 2

of a damaged or otherwise impaired eye lens, said reconstructed lenses not being rejected, not being reabsorbed by the human body, and not causing irritation or other side-effects.

Other objects of the present invention and advantageous features thereof will become apparent as the description

In principle the process of producing material useful in the manufacture of aids to vision, such as contact lenses and lenses for replacing damaged or otherwise impaired natural eye lenses, comprises the following steps.

#### (a) Preparatory step

Human or animal eye lenses are removed histologically from the eye. They are freed of adhering vitreous body (Corpus vitreum or vitreous humor) and of ciliary ligament or body and are decapsulated, i.e., separated from their elastic capsule and suspensory ligaments. The decapsulated lenses are then mechanically separated into their outer or peripheral shells or layers and their inner nuclei (nuclei lentis), i.e., the more difficultly soluble dense inner parts of the crystalline eye lenses. Mechanical separation of the more liquid peripheral part of the lens from the more solid inner part or nucleus of the lens may, for instance, be effected by shaking the eye lenses on a coarse sieve. Such separation may also be effected by the action of suitable solvents which are capable of partly dissolving the outer layer and thus separating it from the nucleus. Suitable solvents are, for instance, urea, lithium thiocyanate, alkali metal hydroxide solutions, or organic solvents such as polyalcohols. Of course, only such dissolving agents and solvents can be used which do not cause any substantial denaturation of the proteins.

As structural material for reconstructing and regenerating aids to vision according to the present invention, there may be used the outer layer or shell of the eye lens as well as its nucleus.

## (b) Preparations of aids to vision from the lens nucleus

(1) When using the nucleus or inner part of the lens as starting material, it is carefully dehydrated under such conditions, at such a temperature and pressure, and so slowly that the water is able to diffuse from the interior of the nucleus to the outside without causing the formation of cracks, fissures, holes. Thereby it is the preferred procedure to keep the moisture differential between the gel of the nucleus and the surrounding atmosphere as low as possible. The dehydrating temperature may be between about 10° C. and about 40° C. The water content of the dehydrated nuclear part of the lens should be at least 10%. A water content substantially lower than 10% will cause the dehydrated material to become brittle and thus to break and become readily crushed on subsequent molding. The resulting dehydrated lens nucleus material has a water content between about 10% and about 40% and preferably between about 10% and about 20%. It is transparent and colorless. It corresponds in its chemical composition to the protein the crystalline lens. It is soluble, although slowly, in weak alkaline, weak acid, urea, and lithium thiocyanate solutions, and in mixtures thereof. The dehydrated material represents the raw material for reconstructing the aids to vision according to the present invention. Careful dehydration under the conditions described above does not cause irreversible change of state of the protein. As a result thereof disintegration of the structure of the lens nucleus material is avoided.

(2) The dehydrated material obtained as described hereinabove is molded into the optical article of the desired shape, for instance, into the shape of contact lenses or lens replacements and others. Such shaping may be effected by means of suitable cutting or machining tools. The preferred procedure, however, is to mold the dehy-